DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

November 5, 2014

Wilson-Cook Medical, Inc.
Doris A. Hawks
Global Regulatory Affairs Specialist
4900 Bethania Station Road
Winston-Salem, NC 27105

Re: K142950
Trade/Device Name: Acrobat Wire Guide
Regulation Number: 21 CFR§ 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCY
Dated: October 14, 2014
Received: October 15, 2014

Dear Doris A. Hawks,

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.

You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Benjamin R. Fisher -A

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*

K142950

Device Name
Acrobat Wire Guide

Indications for Use *(Describe)*
This device is intended to assist in cannulation of the biliary and pancreatic ducts and to aid in bridging difficult strictures during ERCP

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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510(k) Summary

Name:	Wilson-Cook Medical, Inc. / Cook Endoscopy
Address:	4900 Bethania Station Road
	Winston-Salem, North Carolina 27105
Phone:	(336) 744-0157 ext. 6293
Fax:	(336) 201-5994
Contact:	Doris A. Hawks, Global Regulatory Affairs Specialist
Date:	October 6, 2014

Device Name

Trade Name:	Acrobat Calibrated Tip Wire Guide
Common Name:	Wire Guide
Classification Name:	Endoscope Guidewire, Gastroenterology-Urology,
	21 CFR 876.1500, OCY, Class II

Predicate Device

Endoscopic Wire Guide, k122816, cleared October 9, 2012

Intended Use

This device is intended to assist in cannulation of the biliary and pancreatic ducts and to aid in bridging difficult strictures during ERCP.

Device Description

The Acrobat Calibrated Tip Wire Guide is a modification to the existing Endoscopic Wire Guides currently marketed by Wilson-Cook Medical, Inc. The modified wire guide is compatible with a .025", .035" inch or larger inner diameter accessory and available in 205cm, 260cm and 450cm lengths. The wire guide features include marks at 5cm to 25cm at the distal end that provide reference points to indicate movement of wire guide while in use. The distal tip consists of an 11.5cm or 27cm hydrophilic slip-coating.

Substantial Equivalence

Minor design changes were made to the predicate device cleared to market via k122816. These changes include modifications to the diameter, core wire, print marks and coated tip length. The modified device is substantially equivalent to the predicate with respect to the intended use, operating mechanics, materials and the technological characteristics.

Performance Data

The Risk Analysis was completed to access the impact of modifications to the cleared device using the Design Failure Modes and Effects Analysis (DFMEA) method. Design verification and/or validation testing was performed as a result of this risk analysis assessment. Results from design validation and/or verification testing provided reasonable assurance that the modified device is as safe and effective as the predicate device.

Conclusion

We believe risks associated with the modifications to the subject device to be adequately addressed through our Design Control Processes. We believe the proposed device to be substantially equivalent to the named predicate in terms of its intended use, performance characteristics tested.